K000594

DEC - 8 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:
LOCKING SCREW MANDIBULAR RECONSTRUCTION PLATE

General Information

Proprietary Name:	Locking Screw Mandibular Reconstruction Plate
Common Name:	Bone Plate
Classification Name(s):	Bone Plate
Classification Code(s):	76JEY, 872.4760
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Kristyn R. Kelley Project Engineer Quality Assurance and Regulatory Affairs 800-253-7370 x3814
Summary Preparation Date:	February 18, 2000

Device Description

The Locking Screw Mandibular Reconstruction Plates are offered in straight, angled and full mandibular configurations. They are made from titanium, 2.8 mm thick and range in length from 8 screw holes to 30 screw holes. These plates can accept locking screws or standard, non-locking 2.7 and 3.0 mm diameter bone screws.

Intended Use

The Locking Screw Mandibular Reconstruction Plate is intended for mandibular reconstruction following ablative tumor surgery or trauma.

Substantial Equivalence

The Locking Screw Mandibular Reconstruction Plate is substantially equivalent to the Synthes Universal Locking Plate System, K961421.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Ms. Robin L. Rowe
Regulatory Affairs Associate
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K000594
Trade Name: Locking Screw Mandibular Reconstruction Plate
Regulatory Class: II
Product Code: JEY
Dated: September 6, 2000
Received: September 11, 2000

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): not known

Device Name: Locking Screw Mandibular Reconstruction Plate

Indications For Use:

The Locking Screw Mandibular Reconstruction Plate is intended for mandibular reconstruction following ablative tumor surgery or trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000594

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)